

We claim:

1. A composition comprising an aqueous solution of at least 0.01 mg/ml of A β peptide wherein said aqueous solution is maintained at a pH sufficient to solubilize said A β peptide.
2. The composition of claim 1, wherein the solution is maintained at such a suitable pH by use of an effective amount of a pharmaceutically acceptable buffer.
3. A composition comprising a sterile aqueous solution comprising at least 0.01 mg/ml of A β peptide wherein said aqueous solution is maintained at a pH sufficient to solubilize said A β peptide.
4. The composition of claim 3 wherein the solution is maintained at such a pH by use of an effective amount of a pharmaceutically acceptable buffer.
5. The composition of claims 1 or 3, wherein said A β peptide is a long form of A β peptide.
6. The composition of claims 1 or 3, wherein said A β peptide is A β 42.
7. The composition of claims 1 or 3, wherein the pH is about 8.5 to about 12.
8. The composition of claim 7, wherein the pH is about 9 to about 10.
9. The composition of claims 2 or 4, wherein the pharmaceutically acceptable buffer is selected from the group consisting of amino acids, salts and derivatives thereof; pharmaceutically acceptable alkalizers, alkali metal hydroxides and ammonium hydroxides, organic and inorganic acids and salts thereof; and mixtures thereof.
10. The composition of claim 9 wherein the pharmaceutically acceptable buffer is glycine (sodium glycinate) or arginine (arginine hydrochloride).

11. A lyophilized composition of A β peptide which composition is prepared by the process of:

a) freezing a sterile aqueous solution having at least 0.01 mg/ml of A β peptide wherein said aqueous solution is maintained at a pH sufficient to solubilize said A β

5 peptide; and

b) lyophilizing the frozen composition prepared in a) above.

12. The composition of claim 11, wherein said A β peptide is a long form of A β peptide.

10 13. The composition of claim 11, wherein said A β peptide is A β 42.

14. The composition of claim 11, wherein the solution is maintained at such a pH by use of an effective amount of a pharmaceutically acceptable buffer.

15 15. The composition of claim 14, wherein the pharmaceutically acceptable buffer is selected from the group consisting of amino acids, salts and derivatives thereof; pharmaceutically acceptable alkalizers, alkali metal hydroxides and ammonium hydroxides, organic and inorganic acids and salts thereof; and mixtures thereof.

20 16. The composition of claims 1, 3 or 11, wherein the A β peptide is substantially in a random coil conformation.

17. The composition of claims 1, 3 or 11, wherein the A β has a concentration of from about 0.05 mg/ml to about 2.0 mg/ml.

25

18. The composition of claims 1, 3 or 11, wherein the composition further comprises a pharmaceutically acceptable adjuvant.

19. The composition of claim 18, wherein the adjuvant is selected from the group consisting of incomplete Freund's adjuvant; MPL; QS-21; and alum.

30

20. A composition comprising a sterile aqueous peptide suspension of at least 0.1 mg/ml of A β peptide at a pH of about 5 to about 7.

21. The composition of claim 20 wherein the aqueous peptide suspension also contains an effective amount of a pharmaceutically acceptable buffer.

5 22. The composition of claims 20 or 21 wherein said A β is a long form of A β peptide.

23. The composition of claim 22 wherein said A β peptide is A β 42.

10 24. The composition of claim 21 wherein the pharmaceutically acceptable buffer is selected from the group consisting of amino acids, salts and derivatives thereof; pharmaceutically acceptable alkalizers, alkali metal hydroxides and ammonium hydroxides, organic and inorganic acids and salts thereof; and mixtures thereof.

15 25. The composition of claim 20 having 0.1 to 0.8mg/ml of A β 42 peptide, 10 mM glycine, and an acid sufficient to adjust the pH to about 5.5 to about 6.5.

26. The composition of claims 24 or 25 further comprising one or more excipients chosen from the group consisting of tonicity modifiers, surfactants, and wetting agents.

20 27. The composition of claim 24 wherein the composition further comprises a pharmaceutically acceptable adjuvant.

25 28. The composition of claim 26 wherein the composition further comprises a pharmaceutically acceptable adjuvant.

29. The composition of claim 28 wherein the adjuvant is selected from the group consisting of incomplete Freund's adjuvant; MPL; QS-21 and alum.

30 30. The composition of claim 28 having about 0.1 to about 1.0 mg/ml of A β 42 peptide in 10 mM glycine, and at least 0.1 mg/ml of QS-21 in an amount effective to form a visually clear suspension, having a pH of about 6.

31. A process for preparing a sterile composition of a long form of A β peptide comprising:

adjusting the pH of an aqueous solution sufficient to solubilize the A β peptide therein;

5 dissolving into the solution an amount of the A β peptide sufficient to achieve an immunogenic concentration for a mammal; and

filtering the resulting solution through a uniform pore size membrane said pore size being in a range capable of excluding bacteria and passing substantially all of the A β peptide through the membrane.

10

32. The process of claim 31 wherein the filtration is effected with a hydrophilic polymer membrane having a uniform pore size of about 0.22 microns.

15

33. The process of claim 31, wherein the amount of A β peptide recovered after filtration is greater than 50%.

20

34. The process of claim 31, wherein the prefiltration solution contains at least one diluent chosen from the group consisting of pharmaceutically acceptable buffers having a concentration of from about 5 mM to about 45 mM.

35. The process of claim 34, wherein the prefiltration solution contains a tonicity modifying agent from about 0.9% to about 6.0%(w/v).

25

36. The process of claim 34, wherein the prefiltration solution contains a surfactant from about 0.02 to about 1.0 % (w/v).

37. The process of claim 34, wherein the prefiltration solution contains a chelating agent from about 0.1mM to about 1.0 mM.

30

38. The process of claims 34, 35, 36 or 37 wherein the pH of the sterile solution resulting after filtration is adjusted to pH about 5 to about 7 to provide a peptide suspension.

39. A method for preventing or treating Alzheimer's disease in a mammal comprising administering to said mammal a sufficient amount of a sterile aqueous composition comprising at least 0.05 mg/ml of A β peptide to induce an immunogenic response in said mammal wherein said aqueous solution is maintained at a pH sufficient to solubilize said A β peptide.

40. A method of invoking antibody response against an A β peptide in a mammal in need of such an antigenic response comprising:
parenterally administering an immunogenic amount of a sterile composition of a long form of A β .

41. The method of claims 39 or 40, wherein the method further comprises administering a pharmaceutically acceptable adjuvant separately or admixed in within the said sterile composition.

42. The method of claims 39 or 40, wherein the sterile composition is according to claim 30.

43. A composition comprising a suspension of at least 0.1 mg/ml A β peptide and an effective amount of QS-21 to form a visually clear suspension in the pH range of 5 to 7.

44. A composition comprising a suspension of at least 0.1 mg/ml A β peptide and an effective amount of DPPC(dipalmitoyl phosphatidyl chloride) to form a visually clear suspension in the pH range of 5 to 7.

45. Use of a sterile composition of a long form of A β for the manufacture of a medicament for invoking antibody response against an A β peptide.

46. Use of a sterile aqueous composition of A β peptide for the manufacture of a medicament useful for preventing or treating Alzheimer's disease.

47. Use of claim 45 or 46 wherein said medicament further comprising a pharmaceutically acceptable adjuvant.

Add 47